

DOCKET NO.: ALZA-0023 (ARC 2865 N1)
Application No.: 09/802,709
Office Action Dated: September 9, 2003

PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116

REMARKS

Claims 37 and 46-50 are pending in this patent application.

Applicants wish to thank Examiner Fay for taking the time to discuss the outstanding Office Action in a telephonic interview on October 14, 2003.

Claims 36 and 46-50 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Hubbard, *et al.*, *Journal of Pharmaceutical Sciences* 1989, 78:11, 944 ("the Hubbard reference"). Specifically, the Office Action asserts that the graph identified as "Patient Profile 3" on page 945 of the Hubbard reference is anticipatory because it allegedly shows "the use of methylphenidate for the treatment of attention deficit-hyperactivity disorder in an ascending plasma drug formulation up to about 10 hours" (Office Action at page 2). Applicants respectfully request reconsideration of the rejection because the Patient Profile 3 graph does not provide such disclosure.

As was discussed during the interview, both curves presented for Patient Profile 3 show attainment of maximum methylphenidate plasma concentration at about 3.5 hours and a relatively steady concentration decline throughout the remainder of the measured time period. Neither curve shows an ascending plasma concentration over a period of "up to about 10 hours," as alleged in the Office Action, much less Applicants' claimed "substantially ascending [] concentration over a time period of about 5.5 hours following [] administration." Accordingly, the rejection for alleged anticipation should be withdrawn and -- since no other rejection has been entered -- the pending claims should be passed to issue.

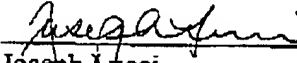
Applicants invite the Examiner to contact the undersigned if any questions arise or further information regarding the instant patent application is needed. In view of the

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foregoing, however, Applicants submit that the pending claims are in condition for immediate allowance, and therefore respectfully request an early indication of allowability.

Date: October 15, 2003



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